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08/722,144

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/722,144	12/12/96	ISHIGURO	2292-038-0

12M1/0109

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EXAMINER

WONG, K

ART UNIT

PAPER NUMBER

1202

DATE MAILED: 01/09/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 11/10/97
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-68 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-68 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449; Paper No(s). 7 (filed 5/11/97)
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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Detailed Action

1. The amendment filed 11/10/97 is acknowledged. Claims 1-68 are pending.
2. Claims 38-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague in being directed to an antibacterial agent without any recitation of a carrier.
3. Claims 36-37 are objected to as substantial duplicates of claim 1. Claims 38-68 are objected to as substantial duplicates of claims 2-32. Please note that, based on MPEP 706.03(k), claims 36-37 or 38-68 would be rejected as substantial duplicates of claims 1 or 2-32 if and when claims 1 or 2-32 are allowed.
4. The rejection of claims 1, 33, 36 and 37 under 35 U.S.C. 103(a) over Afonso et al (US 4,450,579) is maintained. Applicants argued that Afonso et al does not teach cis isomers. However, Afonso et al does teach cis isomers, e.g. 5R,6R,8S (see column 2, line 20, '579). Applicants further argued that the process disclosed in Afonso et al cannot result in the synthesis of the cis compounds, but this argument is not persuasive because Afonso et al, as a U.S. patent, does enable the 5R,6R,8S isomers it discloses.

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5. The rejection of claims 1, 17-19, 32-34, 36 and 37 under 35 U.S.C. 103(a) over Girjavallabhan et al (Ref. R) is maintained. Claims 54-56 are also rejected for similar reasons. Applicants' argument that the fact that instant compounds are cis distinguishes the instant compounds from Ref. R is not persuasive because Compound (23) of Ref. R is cis and is biologically active (see page 3487, Scheme 3, Ref. R).

6. The rejection of claims 1-34, 36 and 37 under 35 U.S.C. 103(a) over Ishiguro et al (Ref. L, JP 04069387 A2; see Ref. T, Derwent abstract C92-059274 and Ref. U, CA 117:90047 for the English abstracts) is maintained. Claims 38-68 are also rejected for similar reasons. Applicants argued that Ishiguro et al fails to suggest the advantageous effects of the present compounds is not persuasive because Ishiguro et al does teach that its cis compounds have antibacterial properties.

7. The rejection of claims 1-4, 7-19, 31-34, 36 and 37 under 35 U.S.C. 103(a) over Sunagawa et al (US 4,472,052) is maintained. Claims 38-57, 60, 63 and 66-68 are also rejected for similar reasons. Applicants' argument that '052 does not specifically suggest 5R,6R,8S isomers is not persuasive because '052 made a number of examples with 5R,6R,8S configuration (e.g. see Examples 1-4, 33, 43-45 and 50).

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8. The rejection of claims 1, 30, 31, 33, 36 and 37 under 35 U.S.C. 103(a) over Menard et al (US 4,272,437) is maintained. Claims 66 and 67 are also rejected for similar reasons. Applicants argued that Menard et al teaches that 1-hydroxyethyl is the most preferred. However, Menard et al does disclose that hydroxy-substituted lower alkyl is preferred. Even though 1-hydroxyethyl is the most preferred, the teachings of a reference are not limited to its most preferred embodiments. So 1-hydroxypropyl, the adjacent homolog of 1-hydroxyethyl, is taught by Menard et al also. Even though Menard et al does not say whether 1'S,5R,6R is advantageous, with a lack of negative teaching of the 1'S,5R,6R configuration Menard et al, one of ordinary skill in the art would still be motivated to make compounds with the 1'S,5R,6R configuration with a reasonable expectation that the resulting compounds would be useful as antibacterial agents.

9. The rejection of claims 1-34, 36 and 37 under 35 U.S.C. 103(a) over Gosteli et al (US 4,692,442) is maintained. Claims 38-68 are also rejected for similar reasons. Applicants argued that Gosteli et al does not teach that the cis isomers are more advantageous than the trans isomers and that all working examples in Gosteli et al are trans isomers. However, the teachings of a reference are not limited to the working examples. Even though, Gosteli et al does not teach that the cis isomers are better than the trans isomers, one of ordinary skill in the art would still find that the cis isomers would have a reasonable expectation of success as antibacterial agents.

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10. The rejection of claims 1-32, 36 and 37 under 35 U.S.C. 103(a) over Leanza et al (US 4,748,162) is maintained. Claims 38-68 are also rejected for similar reasons. Applicants argued that Leanza et al does not state specifically that 1-hydroxypropyl is preferred for the cis isomers. The argument is not persuasive because Leanza et al does prefer 1-hydroxypropyl as a 6-substituent in column 18, line 26. Also 5R,6R cis isomer is exemplified in Example 4, column 23. So an artisan would be motivated to make a cis isomer with 1-hydroxypropyl as the 6-substituent based on Leanza et al.

11. The rejection of claims 1, 36 and 37 under 35 U.S.C. 102(b) over Minamida et al (EP 0 069 373) is maintained. Claims 38-40 are also rejected for similar reasons. Applicants argued that Minamida et al does not specify the steric configuration of 1'-hydroxy. The argument is not persuasive because the last compound in p. 11 of Minamida et al has a cis 5R,6R configuration. Even though said compound is racemic at the 1'-position, the required 1'S configuration for the instant compounds is inherently taught by the racemate of said compound.

12. The rejection of claims 1, 33, 36 and 37 under 35 U.S.C. 103(a) over Minamida et al is maintained. Claims 38-40 are also rejected for similar reasons. Applicants argued that Minamida et al does not specifically teach that 1-hydroxypropyl is particularly advantageous. However, a reference's teachings are not limited to particularly advantageous embodiments. Minamida et al does teach that the penems are useful as antibacterial agents and Minamida et al does exemplify 1-

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hydroxypropyl in p. 11. Applicants then argued that references cited in pp. 16-17 of the amendment show that hydroxyethyl are superior than hydroxypropyl as the 6-substituent. That argument is not persuasive because the experimental details of the comparisons done in these cited references are not available and also Minamida et al does not disclose that 1-hydroxypropyl is inferior than 1-hydroxyethyl at the 6-position. Regarding the steric configuration, it is noted that 1'S,5R,6R is exemplified in Examples 4, 6-8 and 12 in pp. 68-71 and 74 of Minamida et al.

13. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Girijavallabhan et al (Ref. R), which teaches penems with ethylthio at the 2-position useful as antibacterial agents (e.g. see Schemes 2 and 3, p. 3487). Said penems of Ref. R differ from the instant compounds in two ways. First, there is 1-hydroxyethyl instead of 1-hydroxypropyl at the 6-position. But said difference is obvious as discussed before. Second, the penems of Ref. R have ethylthio instead of SH at the 2-position. However, compounds with ethyl instead of H have close structural similarity and compounds of close structural similarity would be expected to have similar properties. Therefore, it would have been obvious to make the instant compounds of claim 35 because, in order to obtain additional bacterial agents, the artisan would have been motivated to modify the penems of Ref. R by replacing 1-hydroxyethyl with 1-hydroxypropyl at the 6-position and by replacing ethyl with H at the 2-position.

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14. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gosteli et al (Ref. D, US 4,692,442), which teaches penems with methylthio at the 2-position useful as antibacterial agents (e.g. see column 11, lines 23-24). Said penems of Gosteli et al differ from the instant compounds in two ways. First, there is 1-hydroxyalkyl instead of 1-hydroxypropyl at the 6-position. But said difference is obvious as discussed before. Second, the penems of Gosteli et al have methylthio instead of SH at the 2-position. However, compounds with methyl instead of H have close structural similarity and compounds of close structural similarity would be expected to have similar properties. Therefore, it would have been obvious to make the instant compounds of claim 35 because, in order to obtain additional bacterial agents, the artisan would have been motivated to modify the penems of Gosteli et al by making 1-hydroxypropyl as the hydroxyalkyl substituent at the 6-position and by replacing methyl with H at the 2-position.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to K.L. Wong via telephone at (703) 308-4723 or facsimile at (703) 308-4556 or (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

K.L.W.
January 5, 1998

K.L. Wong
group 1200